Attachment 8

FEB 11 2009

510 (k) Summary

Submitter's Name and Address	Mylad Orthopedic Solutions, LLC 8803 Windy Creek Way McLean, Virginia 22102 Phone: (703)738-6547 Facsimile: (661)885-4447
Contact Person	Scott Edwards, M.D.
Date of Summary:	December 20, 2008
Proprietary Name of Device:	OlecraNail™ Intramedullary Fixation System
Common/Usual Name:	intramedullary nail
Classification Name:	Rod, Fixation, Intramedullary and Accessories per 21 C.F.R. § 888.3020
Legally Marketed Equivalent Devices:	OlecraNail™ Intramedullary Fixation Device (K081356) Smith and & Nephew TriGen Meta-Nail Retrograde Femoral and Tibial Nails (K061019) Hand Innovations Distal Volar Radius Fracture Repair System (K002775)

Summary of Device:
The OlecraNail™ intramedullary rod is a solid bore, stainless steel, tapered rod that is inserted into a pre-drilled hole into the medullary canal of the proximal ulna. Once the device is in place, a carbon fiber composite guide is used to drill into the bone and insert several screws through the bone and rod to secure all bone fragments and lock the rod into position. During this process, compression at the fracture site may be obtained by manually turning a knob to activate the compression mechanism. After all screws are placed, the guide may then be detached using a break-away mechanism.

Intended Use:
This device is intended for the surgical fixation of all fractures and surgical osteotomies of the proximal ulna in the acute or chronic settings. No changes have occurred to the Intended Use from the previously cleared device, the OlecraNail Intramedullary Fixation System (K081356).

Technological Characteristics of the Device Compared to the Predicate Devices:
The principle of operation of the subject devices is identical to that of the predicates. There are no changes in intended use, performance specifications or method of operation. A review of the test data for the subject devices indicates that they are equivalent to the predicate devices currently in clinical use and are capable of withstanding expected *in vivo* loading without failure.

Substantial equivalence for the OlecraNail™ Intramedullary Fixation System is based on their similarities in indications for use, design features, operational principles, and material composition when compared to the predicate devices cleared under the following submissions: Olecranail™ Intramedullary Fixation System (K081356), Smith & Nephew TriGen Meta-Nail Retrograde Femoral and Tibial Nails (K061019), and Hand Innovations Distal Volar Radius Fracture Repair System (K002775).

Miscellaneous Information:
Carbon fiber composite material, 17-6 Condition H-900, titanium 6-4 alloy are supplied, inspected, and certified to meet ASTM standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mylad Orthopedic Solutions, LLC
% Scott G. Edwards, M.D.
President
8803 Windy Creek Way
McLean, Virginia 22102

FEB 11 2009

Re: K090091
Trade/Device Name: OlecraNail ™ Intramedullary Fixation System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulation Class: Class II
Product Code: HSB
Dated: January 13, 2009
Received: January 14, 2009

Dear Dr. Edwards:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

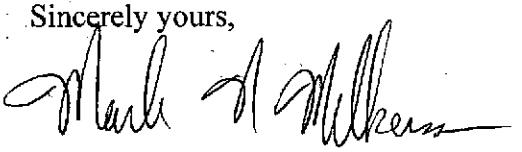
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2

Indications for Use Statement

510(k) Number (if known)	K090091
Device Name	OlecraNail™ Intramedullary Fixation System
Indications for Use	The OlecraNail™ Intramedullary Fixation System and accessories are intended for the surgical fixation of all fractures and surgical osteotomies of the proximal ulna in the acute or chronic setting.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___X___ OR Over-The-Counter Use _____
(Per 21 CFR 801. 109)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090091